JUN - 6 2001

Fonar Corporation
110 Marcus Drive
Melville, New York 11747-4292

May 10,2001

510(k) Summary

Special 510(k) – Device Modification

Submitter Information:

Company: FONAR Corporation
Registration Number 2432211
110 Marcus Drive, Melville, New York 11747-4292

Contact: Luciano Bonanni Executive Vice President
Phone: (631) 694-2929 Fax: (631) 753-5150
E-mail: lbonanni@fonar.com

Reason for Submission: Modification in design and manufacturing process (Energy Source)

Device Designation:

Device Name: Pinnacle Magnetic Resonance Imaging Scanner
Common Name: Magnetic Resonance Imaging Scanner (MRI Scanner)
Classification: System, Nuclear Magnetic Resonance Imaging (NMR/MRI)
Product Code: LNH (formerly 90JAM) Class: 2 Tier: 2
C.F.R. Section 892.1000 Classification Panel: Radiology

Applicable Performance Standards

Intertek Services Corporation has certified the Fonar Quality Management System to the standards EN ISO9001, BS EN9001 and ANSI/ASQC Q9001-1994. Additionally, the Fonar Quad 12000 was awarded the CE certificate and the quality system was certified to the additional standard of EN46001:1997. Our manufacturing systems were tested against the standards IEC 60601-1 (1988), IEC 60601-1-1 (1992-06), IEC 60601-1-2 (1993-04), IEC 60601-2-32 (1994-03), IEC 60601-2-33 (1995-07) and EN1441 (1998). As part of the design/testing process for new products, Fonar utilizes the NEMA standards MS-1 through MS-8 for measuring performance and safety. Images exported from the system utilize the DICOM standard.

Predicate Devices:

The magnet used in the Pinnacle system is substantially equivalent to the magnet used in the 6,000 Gauss (0.6T) Fonar QUAD 12000 magnetic resonance imaging scanner. This magnet was selected as the predicate device because of the similarities in intended use, magnetic field orientation, construction methods, materials and operating characteristics. The QUAD 12000 remains substantially equivalent to its previously approved form.

Description of Device

The Pinnacle magnet follows the same basic design principles as the previously approved Fonar Quad 12000 (K951681) electromagnet. It functions on the same basic operating and physical principles (with the exception of the energy source), is constructed and manufactured with similar materials, and is fabricated in a similar fashion to the previously approved magnet. The primary difference of this new magnet system is that it replaces the resistive magnet coil assembly with a superconductive coil assembly design which is similar to the magnetic field generation systems commonly used for other cryogenless magnet systems in the MRI industry. The operating field strength of the Pinnacle magnet is 6000 gauss (0.6T), which is the same field strength as the QUAD 12000 magnet. The Pinnacle MRI system is basically identical to the Q12000 MRI system in every respect except for the magnet coil assembly and the power supplies and cooling systems necessary to operate the magnet. It is, in summary, a significant equivalent of Fonar's currently approved predicate device. The magnet assembly for the Pinnacle is described beginning in the paragraph below.

The Pinnacle Magnet

The Pinnacle magnet maintains the structural design, "open" scanning environment, and all of the scanning capabilities of the Quad 12000 predicate scanning device. The 0.6T field strength of this magnet produces a signal-to-noise ratio that is equivalent to the signal to noise ratio of the QUAD 12000 scanner. The Pinnacle continues the QUAD 12000 scanners comparable high levels of image quality, combined with equivalent levels of resolution, contrast, precision and speed. The Pinnacle's new design provides a significant increase in magnet stability, resulting in enhancement of image quality and a significant reduction in operating costs. Another advantage is the improvement in overall reliability due to the elimination of equipment commonly used for resistive magnets.

General Description - The Pinnacle Magnet

The FONAR Pinnacle system is a superconductive magnet. The design is identical to the FONAR Quad 12000 "four post" magnet system, but with the resistive magnet coils replaced with superconductive magnet coils. The "cryogenless" design of these superconductive coils, and their associated equipment, is substantially equivalent to other cryogenless systems that have become widespread in the MRI industry. Coil designs similar to those used in the Pinnacle system have become a commonly used design by many systems such as the Toshiba Opart MRT-600 and the GE Signa Advantage SP MRI system. The Pinnacle offers the openness of a Quad 12000 MRI scanner, and the stability, reliability and cost effectiveness of a "cryogenless" superconductive magnet. In addition, maintaining the field strength at 6000 gauss (0.6T) will preserve the signal-to-noise performance of the scanner while retaining the beneficial characteristics of the Quad 12000 scanner.

In the Pinnacle magnet, the poles of the magnet are arranged to establish a magnetic field of known field strength with a limited fringe field, and no "missile effects". The field created between the poles establishes a particular range of precessional frequencies of protons within the subject's atomic nuclei. The magnetic field is created by passing a DC current through the superconductive coil windings where the strength of the magnetic field is directly proportional to the amount of current in the coils. Here, sufficient current will be left in the coil windings to result in a nominal operating magnetic field of 6000 gauss, +/- 5% (0.6T +/-5%). The stability of the field is controlled to a large degree by two factors; first, the efficiency of the superconductive magnet coils themselves, and second, by the superconductive magnet control electronics assembly.

The magnet is designed to operate at resonant frequencies between 24.27 and 26.92 MHz. Precise tuning of the transmitter and receiver coils used within the magnet is accomplished via existing Fonar designed electronic circuits with operating ranges to cover the resonant frequencies. The Pinnacle will use previously approved Fonar receiver coils since they are operating in a field of the same strength and frequency as those used in the Fonar QUAD 12000 MRI scanner. This magnet functions with all imaging pulse sequences available within the current Fonar software releases.

Pinnacle and Predicate Magnet Comparisons

The table of information presented below compares and summarizes the common specifications for the Fonar Pinnacle magnet and the predicate QUAD 12000 magnet and gradient subsystems and also includes the comparative specifications for the Toshiba Opart MRT-600 superconducting magnet. These tables show that the specifications of the new Pinnacle magnet compare favorably to the specifications for Fonar's Quad 12000 magnet, and are therefore substantially equivalent.

MAGNET CONFIGURATIONS			
Magnet Specification	Pinnacle	QUAD 12000	Toshiba Opart MRT-600
Type	Iron-core Superconducting Magnet	Iron-core Electromagnet	Superconducting Magnet
Field Strength	0.6 T ± 5%	0.6 T ± 5%	0.35 T
Calculated SAR	.76 W/kg	0.76 W/kg	<0.244 W/kg
Magnet Power Consumption	N/A	98 kVA	N/A
Magnet Coil Winding Material (Each Pole)	Niobium-Titanium	Copper Bar with hollow core cooling	Niobium-Titanium
Cooling	"Cryogenless" Liquid Helium system with cryocoolers (2)	30 ton closed loop liquid chiller	"Cryogenless" Liquid Helium system with cryocooler
Stability (magnet drift)	long-term << 1 ppm/hr short term < .3 ppm/min	long-term < 2 ppm/hr short term < .3 ppm/min	0.2 ppm/hr
Field Homogeneity	3 ppm within 30 cm DSV 1 ppm within 20 cm DSV	3 ppm within 30 cm DSV 1 ppm within 20 cm DSV	± 2 ppm over 40 cm DSV
Shimming	passive	passive and active	passive
Open Gap™ Configuration	19" vertical clearance 49" horizontal aperture	19" vertical clearance 49" horizontal aperture	21" vertical clearance 39" horizontal aperture
Fringe Field (5 Gauss Line – from magnet center)	horizontal plane – 9' 9" vertical plane – 10' 5"	horizontal plane – 9' 5" vertical plane – 13'	horizontal plane – 9' 6" vertical plane – 12' 1"
Pole Cap Eddy Current Compensation	steel pole with inlaid laminates or self-shielded gradients	steel pole with inlaid laminates or self-shield gradients	N/A
Outer Dimensions (h x l x w)	. 90" x 124" x 124	90" x 124" x 124"	65" x 71" x 84"
Weight (w/ base)	120,000 lbs. (Approx.)	140,000 lbs. (Approx.)	25,250 lbs. (Approx.)

Indications for Use

The Pinnacle MRI System is indicated for use in producing images of multiple planes in the head and body. These images correspond to the distribution of hydrogen nuclei exhibiting nuclear magnetic resonance (NMR) and depend for their contrast principally upon the NMR parameters T_1 (spin-lattice relaxation time) and T_2 (spin-spin relaxation time) and to a much smaller extent on hydrogen nuclei concentration and flow velocity. As a result of the acquisition and processing of the NMR data, these images display the internal structure of the head and body, and when interpreted by a trained physician, can yield diagnostically useful information.

Due to its open design, the Pinnacle can be used for imaging during interventional procedures when performed with MR compatible devices.

Description of Safety and Substantial Equivalence

MRI effectiveness parameters such as spatial resolution, geometric distortion, specification volume, image uniformity, and slice spacing are essentially unchanged by the new magnet. A series of non-clinical tests and a period of human imaging were performed to demonstrate the safety and effectiveness of the Pinnacle magnet, and to establish substantial equivalence to the predicate magnet. All testing was conducted in accordance with current FDA guidance documents and applicable device regulations, such as the NEMA standards. Results from all testing demonstrate substantial equivalence to the predicate device.

Non-Clinical Testing

The following specific parameters have been identified by the FDA as being pertinent to patient safety and highlighted for inclusion in 510(k) submissions. The majority of these concerns are specifically tested by comparison to the NEMA standards, and the results of those tests are not included here. The new magnet does not significantly affect any of these parameters. Some safety-related parameters for the Pinnacle magnet are listed below.

a. Static Field Strength: 0.6T ± 5%
b. Description of operational modes of the system: Normal mode only
c. Potential emergency conditions and means for shutdown:
   The Pinnacle is designed to have two levels of emergency shutdown. These two levels are "MRI Emergency System Shutdown", which will immediately shut down the entire system with the exception of the magnet and cooling system, and "Magnet Emergency", which will initiate an emergency ramp-down (or quench) of the magnet system. The MRI Emergency switch is on the console, and Magnet Emergency switches are located in the console room, magnet room and turret room.
d. Biocompatibility of materials:
   Utilizing the Fonar Risk Management Plan, a risk assessment of the cryogen system was performed by the Fonar Hazards Analysis committee. After reduction, a risk category of III was determined. This reduction was justified by the presence of emergency ventilation systems, warning signs, training, user guide safety descriptions and the improbability of personnel coming into contact with discharging gasses. Other materials that might be exposed to personnel underwent a risk assessment, and were found to have a very low probability of potential injury. These materials were assigned a risk category of IV (negligible risk).

Clinical Testing

A period of human imaging was performed in accordance with current FDA guidance documents and applicable device regulations that demonstrate the clinical utility of the Pinnacle magnet. The images provide verification that the Pinnacle magnet is effective in producing high-quality images with good signal intensity and image uniformity. These clinical tests have provided sufficient experience to demonstrate the substantial equivalency of the Pinnacle magnet to the previously approved Quad 12000 scanner, with no serious malfunctions or adverse effects to patient health or safety reported.

Summary

The material presented within this submission has demonstrated that the Pinnacle magnet is substantially equivalent to the previously approved Quad 12000 scanner system under its current conditions for intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2001

Mr. Luciano Bonanni
Executive Vice President
Fonar Corporation
110 Marcus Drive
MELVILLE NY 11747-4292

Re: K011485
Pinnacle Magnetic Resonance Imaging Scanner
Dated: May 10, 2001
Received: May 15, 2001
Regulatory Class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Bonanni:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

STATEMENT OF INDICATIONS FOR USE

Applicant: FONAR CORPORATION
510(k) Number (if known): K011465
Device Name: Pinnacle Magnetic Resonance Imaging Scanner

Indications For Use:

The Pinnacle Magnetic Resonance Imaging System is indicated for use in producing images of multiple planes in the head and body. These images correspond to the distribution of hydrogen nuclei exhibiting nuclear magnetic resonance (NMR) and depend for their contrast principally upon the NMR parameters T_1 (spin-lattice relaxation time) and T_2 (spin-spin relaxation time) and to a much smaller extent on hydrogen nuclei concentration and flow velocity. As a result of the acquisition and processing of the NMR data, these images display the internal structure of the head and body, and when interpreted by a trained physician, can yield diagnostically useful information.

Due to its open design, the Pinnacle can be used for imaging during interventional procedures when performed with MR compatible devices.

WARNING: This device is limited by U.S. Federal law to investigational use for indications not in the indications statement.

Under the requirements of the law, the non-indicated applications can be used only under an Institutional Review Board approved protocol for a non-significant risk device or an Investigational Device Exemption application approved by the FDA for a significant risk device. The procedures to be followed, under the sponsorship of FONAR Corporation, are determined by the current guidelines established by the FDA, which should provide the IRB with sufficient guidance to determine the level of risk for a MRI device.

WARNING: U.S. Federal law restricts the sale, distribution and use of this device by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER LINE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David C. Seyer
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011485

Prescription Use ✓